K111747

JUL 1 2 2011

6. 510(K) SUMMARY OR 510(K) STATEMENT

Endologix AFX Introducer System
510(k) Summary – K TBD
June 20, 2011

1.	**Company:**	Endologix, Inc. 11 Studebaker Irvine, CA 92618
	Contact:	Janet M. Fauls VP, Regulatory and Clinical Affairs (949) 595-7203 (949) 595-7313 (fax) jfauls@endologix.com
2.	**Proprietary Trade Name:**	Endologix AFX Introducer System
3.	**Classification Name:**	Catheter, Introducer (21 CFR 870.1340)
4.	**Product Code:**	DYB

5. Product Description:

The Endologix AFX Introducer Systems consist of an Introducer Sheath (45 cm working length) and either one or two Dilators. Model S17-45DD contains dual dilators: a dual-lumen dilator for introduction and management of two guidewires; and, a single-lumen dilator. Model S17-45 contains only the single-lumen dilator.

Each AFX Introducer System is enclosed in a sterile package. Each system is compatible with a standard 0.035" guidewire.

- *Introducer Sheath:* The Introducer Sheath provides a conduit for introducing other interventional devices, including guidewires and interventional catheters, into the vasculature. The main components of this assembly are a hydrophilically-coated, PTFE lined, 55D Pebax introducer sheath, acrylobutylstyrene (ABS) hemostasis valve housing with butyl rubber valve, and silicone gasket assembly, 3 way stopcock/valve, and sideport diethylhexyl phthalate (DEHP)-free polyvinylchloride (PVC) tubing. The Pebax introducer sheath also includes an embedded stainless steel braid for increased strength and kink resistance, and embedded Vectran® strands for increased longitudinal strength. The distal tip of the introducer sheath includes an embedded radiopaque marker composed of 90% Platinum/10% Iridium. There are no changes to the Introducer Sheath from that cleared under K110090.

- *Dilators:* The dilators for these systems are used to provide support and stability to the Introducer Sheath during deployment into the vasculature. The dilators are designed specifically for the Endologix AFX Introducer Systems and can accommodate a 0.035" guidewire through the central lumen. One dilator is a single lumen device and the other dilator

is a dual lumen device. Both dilators are composed of 63D Pebax with 30% Barium Sulfate ($BaSO_4$) for radiopacity and include a hydrophilic coating on the outer surface. These dilators are designed in diameter and length to be placed within the AFX Introducer Sheath component. The dilators have a tapered, atraumatic distal tip. The proximal end of the dilators includes a luer port. The dilators provide stiffness to the assembly so that the introducer sheath can be placed within the vasculature during standard vascular access. There are no changes to the Dilators from that cleared under K110090. Model S17-45 contains only the single lumen dilator; Model S17-45DD contains both dilators with the AFX Introducer System within the package.

6. Indications

The Endologix AFX Introducer Systems are intended for use to facilitate the introduction of guidewires, catheters and other medical devices into the vasculature and minimize blood loss associated with such introduction.

7. Substantial Equivalence

Documentation provided includes a detailed comparison which demonstrates that the proposed Endologix AFX Introducer Systems (Model S17-45DD containing dual dilators; Model S17-45 containing only the single-lumen dilator) are substantially equivalent to the predicate Endologix AFX Introducer System (containing the introducer sheath and dual dilators [single-lumen and dual-lumen dilators]) cleared under K110090. The descriptive characteristics of the proposed devices are sufficient to ensure equivalence to the predicate device.

Data contained within the original 510(k) that support the S17-45DD and S17-45 models include functional qualification, ethylene oxide (EtO) gas sterilization validation, 3-year shelf-life packaging qualification, and biocompatibility testing for the intended use as listed below:

Table 7-1: List of Tests Performed to Establish Equivalence to Predicate Device

Test Description	Applicable test standard (s)
Functional/Mechanical Qualification	ISO 10555-1:1995
EtO Gas Sterilization Validation	ANSI/AAMI/ISO 11135-1: 2007 AAMI TIR 28: 2009
3-year Shelf-Life Packaging Qualification	ISO 11607-1:2006
Biocompatibility Testing	ISO 10993-1: 2009

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

JUL 12 2011

Endologix, Inc.
c/o Janet M. Fauls
VP, Regulatory and Clinical Affairs
11 Studebaker
Irvine, CA 92618

Re: K111747
Trade/Device Name: AFX Introducer System
Regulation Number: 21 CFR 870.1340
Regulation Name: Catheter Introducer
Regulatory Class: Class II (two)
Product Code: DYB
Dated: June 21, 2011
Received: June 22, 2011

Dear Ms. Fauls:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number:

Device Name: Endologix AFX Introducer System

Indications for Use: The Endologix AFX Introducer Systems are intended for use to facilitate the introduction of guidewires, catheters, and other medical devices into the vasculature and minimize blood loss associated with such introduction.

Prescription Use __x__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K111747